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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,711	04/20/2001	Darwin J. Prockop	57616-5017US1	6580
7590	02/10/2006		EXAMINER	
DRINKER BIDDLE & REATH LLP One Logan Square 18th & Cherry Streets Philadelphia, PA 19103-6996			KELLY, ROBERT M	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/839,711	PROCKOP ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 November 2005.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 17-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 17-32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/3/05 has been entered.

Claims 1-16 and 33-48 have been cancelled.

Claims 17, 21, 25, and 29-32 have been amended.

Claims 17-32 are presently pending and considered.

### ***Claim Status, Cancelled Claims***

In light of Applicant's cancellation of claims 1-16 and 33-48, all rejections and/or objections to such claims are rendered moot, and thus, are withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-32 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites that the MSC may be administered immediately upon isolation or after not more than 3 passages in culture, and that the isolated MSC is further “short-term cultured cells”. It is unclear how the cells may be administered immediately upon isolation and further be short-term cultured cells.

Claims 18-20 are rejected for depending from a rejected base claim and not overcoming the lack of clarity in such base claim.

Claim 21 recites that the MSC may be administered immediately upon isolation or after not more than 3 passages in culture, and that the isolated MSC is further “short-term cultured cells”. It is unclear how the cells may be administered immediately upon isolation and further be short-term cultured cells.

Claims 22-24 are rejected for depending from a rejected base claim and not overcoming the lack of clarity in such base claim.

Claim 25 recites that the MSC may be administered immediately upon isolation or after not more than 3 passages in culture, and that the isolated MSC is further “short-term cultured cells”. It is unclear how the cells may be administered immediately upon isolation and further be short-term cultured cells.

Claims 26-28 are rejected for depending from a rejected base claim and not overcoming the lack of clarity in such base claim.

Claims 29-32 each recite that the MSC may be administered immediately upon isolation or after not more than 3 passages in culture, and that the isolated MSC is further “short-term cultured cells”. It is unclear how the cells may be administered immediately upon isolation and further be short-term cultured cells.

Claims 17, 21, 25, and 29-32 each recite that the marrow stromal cells are short term cultured cells. However, such limitation is relative and can therefore only be considered term on a relative basis. Applicant has not provided any basis in the claims to which such cells are considered short term. Hence, the limitation is unclear as to its metes and bounds.

Claims 18-20, 22-24, and 26-28 are further rejected for depending from a rejected base claim and not overcoming the lack of clarity in such base claim.

***Claim Rejections - 35 USC § 112 – new matter***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's claims encompass the limitation "short term cultured cells". However, no implicit or explicit support is found in the specification and claims as originally-filed to indicate that Applicant had possession of such a genera. Moreover, such short-term cultured cells must be short term relative to something else. The Artisan would necessarily find that Applicant's claimed limitation was not possessed because the question of whether these cells are short term relative to the doubling-time, differentiation time frame, or relative to something else, may be

what is encompassed. Hence, the Artisan would necessarily not find that Applicant possessed the genera of all short-term cultured marrow stromal cells.

***Response to Argument – new matter***

Applicant's argument of 11/3/05 has been fully considered but is not found persuasive.

Applicant argues that no *in haec verba* requirement is made for demonstration of possession, and further that the specification in teaching three passages *in vitro* prior to administration to an animal, teaches short-term cultured cells (Applicant's argument of 11/3/05, p. 5, last paragraph).

Such is not persuasive. First, while no *in haec verba* requirement is made for the demonstration of possession, Applicant's claimed limitation being rejected is not "no more than three passages", but instead "wherein said isolated marrow stromal cells are short-term cultured cells". Applicant's sole demonstration of any possession is implicit, being that the cells used for transplantation were allowed to reach the third passage (EXAMPLES, p. 15, paragraph 1), and hence possession of only this implicit embodiment is shown. However, even in this example, these cells were cultured for at least three days prior to the argued "short term culture" (Id.). Hence, Applicant's argument similarly does not demonstrate possession of what Applicant argues they have possession of: short-term cultured cells. Finally, as is shown in the rejection for lack of clarity, Applicant's claim limitation is required to depend from something else, being a relative term, and Applicant has not shown possession of all such short-term cultured marrow stromal cells, as short term is necessarily relative. For example, Applicant has not shown possession of short term cultured MSCs relative to the doubling time of a bacterial cell.

Applicant argues that the specification also describes periods of *in vitro* culturing, and hence, such provides the demonstration of possession required (Applicant's argument of 11/3/05, pp. 5-6, paragraph bridging).

Such is not persuasive. Applicant's claimed limitation is to short-term cultured cells, not to various time frames delineated in the specification. Moreover, as is stated above, the Artisan would not know which time frames are short-term cultured cells, as such term is relative to another parameter, and therefore, varies in time frame well beyond any limits provided by the Applicant in the specification.

Applicant cites various case law, averring that their disclosure demonstrates the required possession in the context of the common law (Applicant's arguments of 11/3/05, pp. 6-7).

Such is not persuasive. As is shown above, the Artisan could not ascertain Applicant had possession of the claimed genera at the time of filing, for the reasons given. Applicant's citations of case law, while relevant actually support the Office's conclusions, because even if every nuance is not provided, Applicant must demonstrate possession.

Lastly, with regard to Applicant's argument that the Examiner suggested the limitation to short-term cultured cells, while the Examiner did request Applicant to amend the claims to reflect what they argue is the invention (e.g., Official Action of 8/1/05, p. 9), the Examiner did not state that they may do so without regard to the requirement to demonstrate possession of the invention at the time of filing.

**For the following rejection, it is noted that Applicant's claims are not limited to only administration of the marrow stromal cells, but the composition comprises isolated marrow stromal cells.**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Remes, et al. (1996) Ann. Med., 28: 79-81.

With regard to each method, Remes teaches that it was well known in the art to administer bone marrow, either autologous or allogenic, which is isolated from a patient, and inherently comprises bone marrow stromal cells, to a patient (p. 79, paragraph 1) and are administered by infusion (ABSTRACT). Moreover, it is clear that the methods are involved in treating humans (p. 79, paragraph 1).

With regard to the claims to treating ablated marrow, chemotherapeutically-ablated marrow, and TBI-ablated marrow, Remes directly acknowledges that such is encompassed within such treatments (Id.).

With regard to increasing hematopoiesis, such is the result which is considered to be of import with regard to the method, and therefore, hematopoietic stem cells are considered to be a better source of such cells (p. 79, col. 2).

With regard to rescue or increasing survival of ablated marrows and lethal TBI, such is inherent in the method (p. 79, col. 1).

***Claim Rejections – 35 USC § 103 – Anklesaria/Palsson***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

While the rejections of Claims 17-32 under 35 U.S.C. 103(a) as being unpatentable over Anklesaria '87, and further in view of U.S. Patent No. 5,635,386 to Palsson, et al., hereinafter referred to as "Palsson '386" for reasons of record in the previous Office Actions and for reasons necessitated by the amendments, as evidenced by Shpall, et al. (1997) Annu. Rev. Med., 48: 241-51 and Remes, et al. (1996) Annals Medicine, 28 : 79-81, are withdrawn,

Claims 17-32 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Ankelsaria and U.S. Patent No. 5,635,386 to Palsson, et al., as further evidenced by Shpall, et al. (1997) Annu. Rev. Med., 48: 241-51; Remes, et al. (1996) Annals Medicine, 28 : 79-81, Werts, et al. (1980) Radiation Research, 81 : 20-30, and Piersma, et al. (1983) Brit. J. Haematology, 54: 285-90.

Applicant's claims now contain the limitation that the MSCs are short-term cultured cells. However, given that, as has been demonstrated in the record, that the Artisan would necessarily expand the number of passages to obtain enough MSCs for transplant, on the basis

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that the Artisan would routinely do so, it is obvious that those embodiments that met Applicant's ambiguous short term culture would necessarily be embraced as obvious when it was important to do so to obtain the requisite number of cells from the cells obtained from the donor. (e.g., Official Action of 8/1/05, p. 7, paragraph 2).

The rejections remain the same, however, the Piersma reference is now applied to rebut Applicant's arguments that Ankelsaria and Palsson do not demonstrate that any marrow stromal cells may be used. Specifically, Applicant's argument is that Ankelsaria demonstrates a specific cell strain could be used, and evinces doubt that other MSCs would actually be beneficial in treating bone marrow ablations. However, Piersma demonstrates that other MSCs also work in treating bone marrow ablations (ABSTRACT; p. 287, paragraph 2; p. 288, last paragraph). Hence, Piersma provides specific evidence that at the time of filing the results of Ankelsaria were not considered limiting to that specific cell type used by Ankelsaria, but that any MSC could be used. It is further noted that the CFU-F, the colonies formed and analyzed in Piersma are marrow stroma cells (p. 285, paragraph 1).

***Response to Argument - Anklesaria/Palsson***

Applicant's argument of 11/3/05 has been fully considered but is not found persuasive.

Applicant argues that Ankelsaria teaches away from the invention as claimed, and that there exists no motivation in the Art to combine with the teachings of Palsson, because Ankelsaria's cells were transformed with a nucleic acid, which Applicant avers is well known in the art to be very different and likely malignant (Applicant's argument of 11/3/05, p. 9, paragraphs 1-2).

Such is not persuasive. As has been discussed throughout the prosecution history, Ankelsaria also considered whether these cells were hyperproliferative, but concludes that these cells do not exhibit such characteristics, and the transgene is simply a marker which allows selection of the cells (e.g., Official Action of 8/1/05, p. 9), and hence such is not the case with these cells. Moreover, Applicant's claims do not preclude the use of cells transformed with nucleic acids in the first place. Lastly, given that Ankelsaria demonstrates treatment with MSCs in a mammal, as is shown throughout the prosecution, and the fact that Palsson also teaches, as evidenced by Shpall and Remes, that such MSC therapy was already well established in the art, the Artisan would not recognize Ankelsaria as teaching away or being so distinct as to not be applicable art in an obviousness-type rejection (Official Action of 8/1/05, pp. 5-12).

Applicant argues that short term cultures are inherently different from that of long term cultures, and therefore, Ankelsaria is inherently different and not applicable to the rejection at hand (Applicant's argument of 11/3/05, p. 9, last paragraph).

Such is not persuasive. Applicant fails to understand that Ankelsaria is not used in as an anticipatory reference anymore, but as an obviousness-type rejection, in light of Palsson and as further evidenced by the art. Simply put, Applicant has failed to demonstrate how (i) Ankelsaria is so distinct from Applicant's disclosure, and (ii) how, given the fact that the art already knows how to isolate such cells and expand them, as shown in Palsson and further evidenced by Shpall and Remes, how Applicant's invention is novel and non-obvious over the rejections applied. Simply averring that these cells are different, and therefore not applicable, especially given that the Art already isolated and used the same cells to effect the same methods, does not provide the

structure and steps to make the methods distinct and show what is required to overcome the rejection.

Applicant argues that the Examiner has failed to address that Applicant's invention is actually non-transformed cells (Applicant's argument of 11/3/05, p. 10, paragraph 1).

Such is not persuasive. First, as has already been stated in previous rejections, Applicant's claims are not drawn to non-transformed cells. Second, the Examiner has thoroughly addressed the fact that these cells are not "immortalized" but simply transformed for easy isolation (Official Action of 8/1/05, pp. 6-7, paragraph bridging). Third, Applicant has not shown that these cells are transformed in the terms of being immortal, or even shown why such is so distinct, given what was already known in the art, that it would not be obvious to make the claimed invention. Applicant appears to be belaboring the same points, and no progress is being made.

Applicant argues that Ankelsaria indicates that at the time of publication it was not known if other marrow stromal cells would similarly engraft and support the regeneration of blood cells, and therefore, Ankelsaria is not enabling of other stromal cells (Applicant's argument of 11/3/05, p. 10, paragraph 2).

Such is not persuasive. Ankelsaria alone is not required to be enabled at the time of publication, but in view of the prior art at time of Applicant's filing, when combined with the other art used in the rejection. Basically, by Applicant's argument, Applicant has shown one other cell that supports the same method disclosed by Ankelsaria, and therefore, they get the whole genus, while Ankelsaria gets only what is disclosed, at the time of Applicant's disclosure. Such is incorrect, particularly given that Palsson, as further evidenced by Shpall and Remes and,

more importantly, by Peirsma, had shown that these same cells were well known at the time of invention to apply to more than Ankelsaria's cells, but instead to any MSCs (Official Action of 8/1/05, e.g., p. 10, paragraph 3). Therefore, Ankelsaria and Palsson, as further evidenced by Shpall and Remes, at the time of filing was certainly enabling of the claimed invention.

Applicant argues that the Examiner is combining teachings of bone marrow stromal cells with those of hematopoietic stem cells to render the invention obvious, and such is improper for the rejection under obviousness. Applicant avers that such hematopoietic stem cells have the ability to differentiate into blood cells, whereas bone marrow stromal cells are at least multi-potent, and therefore, there is motivation to combine teachings (Applicant's argument of 11/3/05, p. 10, paragraph 3-p. 11, paragraph 1).

Such is not persuasive. First, Applicant is arguing that hematopoietic stem cells are more limited than bone marrow stromal cells, and therefore, the stromal cells would not differentiate into hematopoietic cells. This is not consistent, as broader abilities to differentiate do not exclude the possibility to differentiate into hematopoietic cells. Second, as shown by Ankelsaria, and further shown by Palsson, these cells may be used in humans, as further evidenced by Shpall, Remes, and particularly by Peirsma. Hence, the motivation to combine teachings is that, from Applicant's arguments, Peirsma demonstrates it was well known in the art that any MSC could be used, and is not limited to those of the cell line of Ankelsaria.

Applicant argues that Palsson does not teach administration of bone marrow stromal cells to a mammal (Applicant's argument of 11/3/05, last paragraph).

Such is not persuasive. Palsson teaches that the disclosed cultures provide for improved methods of bone marrow transplantation (ABSTRACT). Moreover, given what was known in

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the art at the time of Applicant's invention, it was obvious to use the marrow stromal cells, whether cultured for expansion, or administered upon isolation, as further evidenced by Shpall, Remes and Peirsma. Such expansions are considered trivial in the art and simply depend from how many cells you have to start and how many you wish to transplant.

Applicant argues that Palsson teaches that the marrow stromal cells may or may not be present in the cultures of the invention, and that therefore, Palsson only teaches hematopoietic stem cells, optionally containing MSCs (Applicant's argument of 11/3/05, p. 12, paragraph 1).

Such is not persuasive. Palsson teaches marrow stromal cells may or may not be present, but the art further demonstrates that marrow stromal cells may be used, as evidenced by Shpall, Remes and Peirsma. Moreover, Applicant has not excluded hematopoietic progenitor cells from the claims. Simply put, in either case, it was well recognized in the art that the marrow stromal cells could be used to regenerate marrow, and Peirsma particularly answers Applicant's questions as to whether the results of Ankelsaria were limited to Ankelsaria's invention: Peirsma teaches another animal, and another cell. It is clear that all of Applicant's lack of expectation of success is overcome by Peirsma.

Applicant again argues that Ankelsaria is limited to its teachings, arguing against reasonable predictability at the time publication of Ankelsaria (Applicant's argument of 11/3/05, paragraph 2).

Such is not persuasive. As has been argued above, Ankelsaria, as further evidenced by Peirsma demonstrates that at the time of Applicant's invention, there was a reasonable expectation in the art for any MSC to be used.

Applicant takes issue with the Examiner's assertion that if two references disclose the same thing at the same time, they necessarily enable the same amount of subject matter, arguing that bone marrow stromal cells are different from bone marrow transplantation (Applicant's argument of 11/3/05, paragraph 3).

Such is not persuasive. Applicant's argument is misplaced as Ankelsaria did not use bone marrow transplantation, but instead used marrow stromal cells (Ankelsaria, ABSTRACT). Moreover, as demonstrated by Peirsma, Applicant's arguments concerning reasonable predictability are overcome because Peirsma demonstrates the method applicable to any marrow stromal cells, and not just the cell line of Ankelsaria.

Applicant argues that Palsson does not overcome the problems with Ankelsaria, because Palsson is limited to long term cultures (Applicant's argument of 11/3/05, p. 13, paragraph 1).

Such is not persuasive. Applicant's definition of long-term is still at issue, and it is not clear what short-term actually means. Moreover, Palsson simply is not used to demonstrate long term culture, but to demonstrate that the methods were used in humans, and even to the point that improved sources of the cells is being supplied. Further, going back to short term cultures, it is clear from Applicant's own disclosure, that the cells are previously passaged before the three passages of MSC is used (Applicant's EXAMPLES). Hence, what is long term or short term is ambiguous at best.

Applicant broadly avers that the teachings cannot be combined, characterizing the teachings as not teaching the administration of bone marrow stromal cells (Applicant's argument of 11/3/05, p. 13, paragraph 3).

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Such is not persuasive. The teachings demonstrate that it was well known in the art to perform such transplants, and that the cells comprised MSCs. Moreover, the newly-cited reference of Peirsma demonstrates that MSCs in general could be used alone, rather than mixtures of cells.

Applicant argues that bone marrow transplantation is not the same as marrow stromal cell transplantation, and therefore, the Art cited does not obviate Applicant's invention (Applicant's argument of 11/3/05, pp. 13-14, paragraph bridging).

Such is not persuasive. Applicant's argument is inconsistent with the language of the claims. Applicant's claims encompass administration of bone marrow, as long as it comprises marrow stromal cells, and may be cultured up to three passages. Moreover, the Examiner hopes, Applicant now understands that the Art at the time of filing demonstrates that the Artisan would have found Ankelsaria (as evidenced by Peirsma) to be enabled for more than the cell type used in Ankelsaria.

*Note to Applicant*

Applicant appears to believe that their disclosure of essentially the same thing as Ankelsaria enables their invention at the time of invention, with a breadth of many species and cell types, but that Ankelsaria's invention is not obvious for any more than what is shown in the reference itself, at the time of Applicant's invention. On the hand, the Examiner believes that the art sufficiently demonstrates those aspects claimed by Applicant are enabled by the Ankelsaria reference. Further to this point, if two references disclose the same thing at the same time, they necessarily enable, and therefore provide a reasonable expectation of success for the same

subject matter. The Examiner has demonstrated that bone marrow transplants were known in the art, that the stromal cells were the reasons for such transplants, and that other references recognize the utilization of stromal cells in, *inter alia*, humans, even to the point of suggesting a different source for equivalent cells (i.e., peripheral blood). Such suggestion and application of a different source would not be made if the Art did not have the field pretty well characterized. Moreover, with regard to the differences in Ankelsaria, those differences between Ankelsaria and Applicant's disclosure encompass such structure that would not be detrimental to a reasonable expectation of success (i.e., the transformation yielded cells with equivalent function). Moreover, the whole of the Palsson reference takes for granted that these cells are used in such methods of transplantation. Hence, the only conclusion that can be reasonably made by the Artisan is that Applicant's claimed methods are obvious.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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